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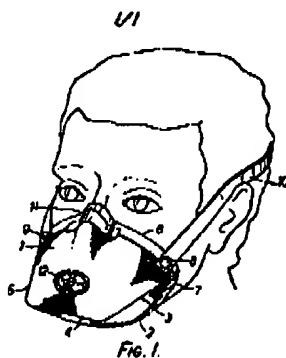
REMARKS

Claim 33 has been amended to specify that the orifice has a cross-sectional area greater than about 2 square centimeters. Dependent claims 86-88 have also been added, which dependent claims further describe the cross-sectional area of the orifice.

Claims 30-37, 50-53, and 55-58 have been provisionally rejected under the judicially-created doctrine of obviousness-type double patenting. On March 27, 2003, applicants filed a Terminal Disclaimer with the United States Patent and Trademark Office. Applicants believe that the submission of the Terminal Disclaimer eliminates all issues pertaining to the double patenting rejection.

Claims 3-37, 50-53, 55-63, 65-72, and 76-78 have been rejected as being unpatentable over the '516 British patent to Simpson et al. (Simpson) in view of the '168 patent to McKim. Applicants respectfully submit that this rejection cannot be sustained for the following reasons.

Firstly, neither Simpson nor McKim teaches or suggests placing an exhalation valve on a filtering face mask directly in front of where the wearer's mouth would be when the mask is worn:



Nor does either reference suggest that the orifice should have a cross-sectional area of greater than about 2 square centimeters. In Simpson, the exhalation valve is placed on the top of the duck-billed mask so that the valve can take advantage of gravity to keep the flap pressed against the seal surface under neutral conditions, that is, when a wearer is neither inhaling nor exhaling. Simpson needs to place its valve in this particular location because the flap is not pressed towards the seal surface in an abutting relationship with it, under any orientation of the valve, when a fluid is not passing through the orifice. The Examiner's attention is directed in particular to Figure 2, where it can be readily noticed that there is no prestress imposed upon the flap that

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would cause it to be pressed towards the seal surface when a fluid is not passing through the valve orifice:

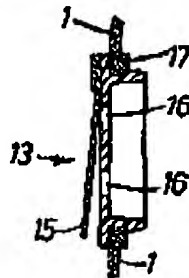


FIG. 2.

The Simpson flap 15 can only be pressed towards the seal surface under the force of gravity when the mask is oriented in an upright position. When a wearer tips their head downward, the mask cannot take advantage of gravity, and the flap may droop away from the seal surface. This movement can allow contaminants to enter the mask interior. In regard to the size of the orifice, Simpson only shows two small openings 16. McKim does not address the placement of the valve on a face mask because it refers to a reed valve for a 2-cycle engine. It also makes no mention of the size of an exhalation valve orifice.

Secondly, neither Simpson nor McKim teach or suggest the benefits of the present invention. As the Examiner is aware, the advantages that an invention possesses must be considered under the "subject matter as a whole" provision of 35 USC § 103. As demonstrated in the Examples, applicants' inhalation valve is so efficient that it can purge more than 100% of the air that is present within the interior of the mask. This provides a cool-air aspiration effect, where cool ambient air is drawn into the mask interior during an exhalation. For a better understanding of this effect, the Examiner's attention is directed to Examples 8-13 set forth on pages 21-23 of the specification. Please also see page 5 of applicants' specification. In addition to providing an aspiration effect, the filtering face mask of the present invention can also demonstrate a lower airflow resistance force, which enables the exhalation valve to open easier.

Neither Simpson nor McKim provide any description of the aspiration effect or the structure that is necessary to provide it. Applicants' claims specify that the exhalation valve should be disposed directly in front of where the wearer's mouth would be when the mask is worn and that the orifice should have a cross-sectional area of greater than about 2 square

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centimeters. As indicated in applicants' specification on page 5, a greater percentage of exhaled air can be purged through the exhalation valve of applicants' face mask, and, after an initial positive pressure to open valve, the pressure inside the mask can decrease and, in some cases, become negative during an exhalation. These two attributes can be achieved by the positioning of the exhalation valve directly in front of the wearer's mouth and by defining a preferred cross-sectional area for the orifice of the flapper-style exhalation valve. Further, neither reference addresses the ability to keep contaminants out of the mask interior by keeping the valve closed under any orientation of the mask. Because Simpson and McKim both fail to appreciate the structure and benefits that stem from applicants' invention, applicants' invention should also be patentable for this reason.

Thirdly, applicants' claims are patentable over Simpson and McKim because McKim cannot be applied as a secondary reference in making this rejection. McKim is not directed to an analogous art that would allow it to be cited under 35 USC § 103. As the Examiner is aware, a reference cannot be considered sufficiently analogous and thus relevant for determining obviousness unless it is either (1) within the field of the inventor's endeavor, or (2) is reasonably pertinent to the particular problem that confronted the inventor.¹ Applicants' invention resides in the field of filtering face masks that use exhalation valves. McKim does not reside within this field of endeavor: it resides in the field of gasoline engines that use reed valves.

McKim shows a curved seat reed valve that is designed for use in a 2-cycle engine, which would turn at speeds as high as 10,000 or 12,000 revolutions per minute. In contrast, applicants' invention pertains to a filtering face mask that employs an exhalation valve, which opens in response to a wearer's breathing. Castiglione explained in his November 15, 1999 Affidavit why McKim does not reside in the field of endeavor of applicants' invention:

The field of endeavor for a filtering face mask is very different from the field of endeavor of a curved seat reed valve that is used in a high-speed engine. Persons of ordinary skill in the field of designing filtering face masks do not consult documents that describe valves for gasoline engines in developing respiratory products. Exhalation valves for respirators operate under very different conditions from valves that are used in gasoline engines and require extraordinary different design parameters.

¹ *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992).

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Another investigator who works in the filtering face mask field, John L. Bowers, explains in more detail why McKim is not in the field of endeavor of a person of ordinary skill in the art designing exhalation valves:

My review of the McKim patent shows a curved seat reed valve that is designed for use in a high-speed engine, which could turn at speeds as possibly as high as 10,000 or 12,000 revolutions per minute (rpm). The reed valve described in McKim is indicated to be particularly suited for a high speed operation where opening and closing forces are large. McKim states these forces can cause the valve to bounce (an apparent elastic recoil from impact). The stated goals in McKim are full and rapid opening, quick and complete closing, and eliminating float and bounce.

The field of the above-captioned '877 invention pertains to a filtering face mask that employs an exhalation valve. A filtering face mask is worn over the nose and mouth of a person for filtering contaminants that may be present in the ambient air. Filtering face masks commonly employ exhalation valves to allow warm, moist, exhaled air to be rapidly purged from the mask interior. The exhalation valves are used to improve wearer comfort. These valves generally operate at normal room temperatures and pressures.

The field of endeavor for filtering face mask is very different from the field of endeavor of a reed valve that is used in a two-cycle engine. Exhalation valves for respirators operate under very different conditions from valves that are used in two-cycle engines and require notably different design parameters. The valve that is described in McKim has very rapid opening and closing requirements (thousands of openings and closings per minute) and operates under temperatures and pressures that differ substantially from the requirements of exhalation valves, which open and close under the much slower pace of a wearer's breathing and under temperatures and pressures that tend to vary only from the ambient to that exhibited by the wearer's exhaled air. Thus, persons of ordinary skill in the field of designing filtering face masks, to the best of my knowledge and experience, do not find valves for two-cycle engines to be in their field of endeavor and therefore do not consult documents that describe valves for these engines when developing new respiratory products.

Bowers' Affidavit, paragraphs 11-13. Another person skilled in the field of exhalation valves for filtering face masks, Frank Fabin, who has worked on one design team and led another design team in the development of a new exhalation valve, stated the following with respect to McKim:

My review of the McKim patent reveals a curved seat reed valve that is suitable for use in high rpm two-cycle engines. The reed valve comprises a thin, normally flat, single thickness, springy, sheet material, which, when relieved of external stresses will lie flat, but which is flexed lengthwise to define a curve. The reed valve is disclosed to be made of a spring sheet material, such as, for example,

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shim stock. The reed valve is disclosed to bear throughout its length against a valve seat, with the seating bias at the free end of the reed being as great as, or greater than, that throughout the remainder of the reed. The reed valve is indicated to be designed to seat quickly, effectively, and without float or bounce after each opening. The patent indicates that the reed valve is adaptable for use within an extremely high-speed engine, for example, one that will turn at a speed on the order of 10,000 or 12,000 revolutions per minute or at more modest speeds of 5,000 to 6,000 rpms.

In my approximately 24 years of working in occupational health, I have not — nor am I aware of another person who works in this field who has — consulted a reference in the reed valve art for gasoline engines to obtain solutions to problems encountered in developing exhalation valves that are used on filtering face masks.

Filtering face masks possess the problem of creating a warm, moist, high CO₂ content environment around the nose and mouth of a person who wears a filtering face mask. Investigators in this field have pursued a goal of purging from the mask interior the largest amount of fluid possible while using the least amount of energy. Investigators therefore have pursued the particular goal of designing exhalation valves that open easily in response to the exhalation pressure developed in the mask interior during an exhalation. Exhalation valves that open under minimal pressure allow the warm, moist high CO₂ content air, to be more easily removed from the mask interior and thus require the wearer to expend less energy to operate the valve over an extended period of time. Exhalation valves typically operate under ambient environmental conditions in response to exhalation pressures generated by the wearer. These conditions are remarkably different from the environment (for example, temperatures and pressures) under which a reed valve operates in a two-cycle gasoline engine. The flexible flaps that are used in exhalation valves do not deal with problems of float, or flutter from bounce in closing like the reed valves described by McKim. The opening and closing of an exhalation valve occurs in cadence with a wearer's breathing pace, which is orders of magnitude less than the high rpms under which gasoline engines operate at. For these reasons and others, persons of ordinary skill in the filtering face mask and exhalation valve art, as far as I am aware, do not examine documents that pertain to reed valves for two-cycle gasoline engines in designing filtering face masks and the exhalation valves that are used on them. Documents that describe reed valves for two-cycle gasoline engines are not in the field of endeavor of persons who design exhalation valves for filtering face masks.

Fabin Affidavit, paragraphs 8-10 (December 10, 2001). In view of this evidence, it is clear that McKim does not reside in the field of endeavor of a person who designs exhalation valves for use on filtering face masks. Because the Examiner has not put forward any evidence to the contrary, the only conclusion that can be reached is that McKim is not in applicants' field of endeavor.

Since the first element of the two-part test for evaluating whether a reference is analogous has not been satisfied, it therefore is necessary to consider whether the McKim reference is

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reasonably pertinent to the particular problem that concerned applicants. The Federal Circuit has explained that *the USPTO needs to consider the purposes of the reference disclosure and the invention* in determining whether a reference meets the second prong of the two-part test:

A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor's endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem. **Thus, the purposes of both the invention and the prior art are important in determining whether the reference is reasonably pertinent to the problem the invention attempts to solve.** If a reference disclosure has the same purpose as the claimed invention, the reference relates to the same problem, and that fact supports use of that reference in an obviousness rejection. An inventor may well have been motivated to consider the reference when making his invention. **If it is directed to a different purpose, the inventor would accordingly have had less motivation or occasion to consider it (emphasis added).²**

In developing their invention, applicants sought to produce an exhalation valve that minimized exhalation pressure needed to open the valve and allowed a greater percentage of exhaled air to be purged through the exhalation valve to improve wearer comfort (see applicants' specification at page 3, line 25 to page 5, line 34 and Examples 4-6 and 8-13). The McKim reference, however, deals with solving the problem of float or bounce, which may occur when a 2-cycle engine is operating at high rpms (see McKim at column 1, lines 20-24 and column 2, lines 55-62). McKim's concern for controlling float or bounce is not reasonably pertinent to the problems that applicants were involved with — namely, providing comfort to the mask wearer by allowing the valve to open under minimal pressure and enabling a greater percentage of exhaled air to be purged through from the mask interior through the valve. As stated in the Bowers Declaration, investigators who work in the field of exhalation valves for filtering face masks are not concerned with problems of float or bounce:

In exhalation valves for filtering face masks, the speeds for opening and closing is not a primary design parameter. There is no incumbent need to rapidly fill or exhaust a combustion chamber. Further, under the airflows and pressure drops that are encountered in a filtering face mask, "bounce or float" is not an occurring event or a problem that investigators in the exhalation valve art need to deal with. Investigators who design exhalation valves for filtering face masks seek to produce exhaust valves that remain closed between breaths and that minimize the force or pressure needed to open the valve from its normally closed position. This particular design goal is not compatible with or comparable to fast-

² *In re Clay*, 23 USPQ2d 1058, 1061 (Fed. Cir. 1992).

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closing valves that require high forces for rapidly opening and closing. Exhalation valves tend to open and close at the rate of a person's breathing, which is about 20 to 60 cycles per minute. In contrast, the McKim valve is designed to operate at speeds as high as 10,000 to 12,000 revolutions per minute. The flow volumes and flap stiffness are orders of magnitude higher for valves that are used in combustion engines as opposed to valves that are used on respiratory masks. For these reasons, a person of ordinary skill in the filtering face mask art would not, in my view, have found the McKim patent to be reasonably pertinent to the problems that are encountered in the development of an exhalation valve for a filtering face mask. McKim would not be a reference that would have logically commended itself to the attention of persons of ordinary skill in developing new exhalation valves for filtering face masks. I have not, nor have I witnessed, anyone who is skilled in the field of developing filtering face masks, look at the art of valves for two-cycle engines for solutions to problems confronted by them in the exhalation valve art.

The Castiglione and Fabin declarations discussed above also explain how McKim is concerned with a problem that is of no concern to the purpose of the present invention. Because the purpose of applicants' invention is not pertinent to the problem that McKim dealt with, namely float or bounce, the second prong of the test for qualifying as an analogous reference also has not been met. A person possessing ordinary skill in the art of filtering face masks that use exhalation valves would not reasonably have been expected to solve the problem of lowering the airflow resistance force needed to open an exhalation valve through considering a reference that deals with eliminating float or bounce in a valve reed in a 2-cycle gasoline engine.

In the leading case that deals with "analogousness" under part (2) of the test, the Federal Circuit has explained that the USPTO needs to consider the purposes of the reference disclosure *and* the invention in determining whether a reference is reasonably pertinent to the particular problem that confronted the inventor.³ In *In re Clay*, the Federal Circuit found the cited reference to be not analogous when (1) the prior art taught the use of a gel within a natural, underground, oil-bearing formation to channel flow in a desired direction and (2) the applicant, Clay, had invented the use of a gel to fill the confined dead volume of a man-made storage tank.

³ *In re Clay*, 23 USPQ2d 1058, 1061 (Fed. Cir. 1992) ("A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor's endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem. Thus, the purposes of both the invention and the prior art are important in determining whether the reference is reasonably pertinent to the problem the invention attempts to solve. If a reference disclosure has the same purpose as the claimed invention, the reference relates to the same problem, and that fact supports use of that reference in an obviousness rejection. An inventor may well have been motivated to consider the reference when making his invention. If it is directed to a different purpose, the inventor would accordingly have had less motivation or occasion to consider it (emphasis added)")

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Although the inventor Clay and the prior art (Sydansk) both described technology that related to the use of gels in the petroleum industry, *the prior art Sydansk reference was found to be nonanalogous because the purpose of the Sydansk teachings were different from the purpose of the Clay invention.* Sydansk was faced with the problem of recovering oil from rock, which was not pertinent to the problem with which Clay was involved, namely, preventing loss of stored product in a tank's dead volume. The court also recognized that the subterranean formation of Sydansk was not structurally similar to and did not operate under the same temperature and pressure and did not function like Clay's storage tanks.⁴

As in *In re Clay*, the McKim reference also does not have the same purpose as applicants' invention, it does not operate under the same temperature and pressure, and it does not function like the claimed invention. Float or bounce is a problem that occurs when 2-cycle engines operated at high rpms (10,000 to 12,000 rpms). It has not been a problem that occurs in exhalation valves, which open and close in cadence with a person's breathing, about 20 to 60 cycles per minute. In addition, internal combustion engines operate at extraordinarily higher temperatures and pressures than a person's exhalation breath and are not powered by a person's lungs but by gasoline combustion. Finally, McKim's valve is used for intake into a combustion cylinder while the present valve is used for exhaust from the interior gas space of a mask.

Applicants accordingly encourage the Examiner to consider the *In re Clay* decision in light of the present rejection.⁵ A summary of the facts in *In re Clay* are provided below for ease of reference:

⁴ See, *Clay*, 23 USPQ2d at 1601 ("Moreover, the subterranean formation of Sydansk is not structurally similar to, does not operate under the same temperature and pressure as, and does not function like Clay's storage tanks.").
⁵ See also, *SRI Int'l, Inc. v. Advanced Tech. Lab.*, 45 F.3d 443, 445 (Fed. Cir. 1995) ("The problem Green solved was how to compensate for changes in the spectral distribution of the return ultrasonic signal, with time or depth of penetration into a living organ, for enhanced image resolution and/or signal to noise ratio. The Minton reference, which relates to seismic prospecting circa 1946, almost thirty years prior to Green's filing date, would not have logically commended itself to Green's attention in considering how to compensate for changes in the spectral distribution of a received ultrasonic signal in an object such as a body part."); *In re Green*, 22 F.3d 1104, 1105 (Fed. Cir. 1994) ("A person of ordinary skill in the aircraft vane art simply would not find a 1919 reference about broken blades in a pugging mill reasonably pertinent to this problem."); *In re Butera*, 1 F.3d 1252, 1253, 28 USPQ2d 1399, 1400 (Fed. Cir. 1993) ("Butera's design is for air fresheners and insect repellents, while Hodge's is for metal ball anodes. The design of Hodge involves a different type of article from Butera's design and it is not analogous. One designing a combined insect repellent and air freshener would therefore not have reason to know of or look to a design for a metal ball anode. Since Hodge is not analogous, the Board clearly erred in finding Hodge to be citable as prior art. Therefore there was no basis for rejecting Butera's claimed design as obvious."); *Wang Laboratories, Inc. v. Toshiba Corp.*, 993 F.2d 858, 864, 26 USPQ2d 1767, 177_ (Fed. Cir. 1993) ("Wang's SIMMs were designed to provide compact computer memory with minimum size, low cost, easy repairability, and easy expandability. In contrast, the Allen-Bradley patent relates to a memory circuit for a larger, more costly industrial controller. SRAMs were used by Allen-Bradley because of their intended industrial environment. According to Dr. Frey, size was not a consideration in the Allen-Bradley work. Thus, there is substantial evidence in the record to support a finding that the Allen-Bradley prior art is not reasonably pertinent and is not analogous.").

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In re Clay	Result: reference <u>not</u> analogous					
	Description	Problem to be Solved	Purpose	Operating Conditions	Similarities	Differences
Clay	use of gel to displace liquid product from tank dead volume	preventing loss of stored product to tank dead volume	to displace liquid product from dead tank volume	<ul style="list-style-type: none">subterranean rockhigh temps (115°C) and bore pressures	both used in petroleum industry	different purposes and operating under different temperatures and pressures
Prior Art Sydansk	use of gel to fill anomalies in natural oil-bearing conditions	recovering oil from rock	to channel flow in a desired direction	<ul style="list-style-type: none">made storage tankambient temp and pressure		
In re Japuntich et al.	Result: not yet decided					
Applicants' Invention	use of a new flapper-style exhalation valve in a filtering face mask	keeping valve closed under any orientation while allowing low pressure drop during an exhalation	to allow valve to open easier during an exhalation but remain closed under neutral conditions	<ul style="list-style-type: none">exhale valve on face mask bodybody temperatureslow pressurescadence of person's breathing	both relate to valves	different purposes and operating under different temperatures, pressures, and speeds
McKim	use of new reed intake valve in a two-stroke engine	stopping flutter or bounce of reed valve while operating under high RPM conditions	to eliminate float or bounce of valve reed to improve power and efficiency of engine	<ul style="list-style-type: none">intake valve on 2-cycle enginehigh tempshigh pressurehigh speeds (10-12,000 rpms)		

The Federal Circuit has stated that when the reference "is directed to a different purpose [than the applicants' invention], the inventor would accordingly have less motivation or occasion to consider it" and therefore it would not be analogous.⁶ Because only the purpose of McKim's valve has been evaluated in determining whether it is analogous, the Examiner has erred in making the assessment of whether the reference is properly analogous. This error, in turn, has caused the Section 103 rejection to be improperly maintained.

Fourthly, even if McKim was found to be an analogous reference, a person of ordinary skill still would not have been led to applicants' invention because the structure of the reed valve

⁶ *Id.*

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disclosed in McKim would not answer the required properties of applicants' valve. There is no evidence that the McKim reed valve would demonstrate the required flexibility of applicants' flexible flap. Applicants have defined the term "flexible" to mean that "the flap can form or bend in the form of a self-supporting arc when secured at one end as a cantilever and viewed from a side elevation (see, e.g., Fig. 5)."⁷ The flap that is described in McKim is made of "spring sheet material, such as, for example, shim stock" (column 1, lines 59-61). McKim therefore is not describing a flexible flap that would be suitable for use in an exhalation valve. This fact is confirmed by Richard Betts, a person skilled in the art of two-cycle engines:

Since 1965, the 2-cycle engines that I have either constructed or worked on have used a reed valve of varying degrees of stiffness. None of the reed valves that I have encountered, however, were "flexible" as the term has been defined in the above-captioned patent application and recited in paragraph 4 above. Reed valves that are used on 2-cycle engines can bend when exposed to a force such as shown in Fig. 3 of the McKim patent. The reed valves, however, are not so flexible that they will bend in the form of a self-supporting arc when secured at one end as a cantilever. Reed valves do not bend in the form of such an arc in response to the mere force of gravity. If the valves were constructed to have that degree of flexibility, the 2-cycle engines in which they were used would surely not be operative. If secured at one end as a cantilever and having a free end that projects from the point of securement, a reed valve would project in an essentially straight line when viewed from a side elevation. The degree of stiffness that reed valves possess are orders of magnitude greater than the flexible flaps that are used on exhalation valves.

Declaration of Richard Betts, paragraph 5 (December 7, 2001). Because McKim's valve reed is so structurally different from the flexible flap that is used in the present invention, there would be no reason to expect — and there is no evidence in this record to indicate otherwise — that McKim's method of mounting its stiff valve reed would be suitable for a more highly flexible flap that is used on an exhalation valve. Further, the conditions under which the McKim reed valve operates (high pressure, high temperatures, 10,000 or so cycles per minute) is so remarkably different from the conditions under which an exhalation valve operates (lung pressure, exhaled air temperatures, and breathing cycles of 20-60 per minute), that there can be no expectation that any structure described in McKim would be suitable to produce an invention like the one under consideration here. Thus,

⁷ Applicants' specification at page 7, lines 11-14.

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the mounting requirements for the McKim cannot be transferred to an exhalation valve like Simpson's without some clear teaching or suggestion to do so.

Fifthly, the rejection cannot be sustained because there is no teaching or suggestion to combine Simpson and McKim. The record is devoid of any teaching, suggestion, or motivation to combine the pertinent teachings of Simpson and McKim. As the Board is aware, an obviousness rejection cannot be sustained, based on a combination of references, without any evidence of why a person of ordinary skill would have been motivated to combine the pertinent teachings.⁸ The suggestion to make the combination must come from the prior art.⁹ It is not enough to simply identify each claimed element in the prior art.¹⁰ "The factual inquiry whether to combine references must be thorough and searching. It must be based on objective evidence of record. This precedent has been reinforced in myriad decisions, and cannot be dispensed with."¹¹

Simpson's teachings are mainly concerned with producing a face mask that is in the shape of a pouch and that has an exhalation valve. Simpson's valve teachings are not concerned so much with showing how to make a low pressure drop valve that can remain closed under a variety of orientations as they are concerned with simply illustrating alternative valves that could be used on its pouch-shaped mask. And McKim's teachings are for providing a curved reed valve seat on a 2-cycle gasoline engine to reduce float or bounce. The Examiner states on page 5 of the January 28, 2003 Office Action that the reason for combination of Simpson et al. with McKim is because "it would have provided for seating quickly, effectively, and without float or bounce after each opening as taught by McKim." Although not necessary to overcome the rejection, applicants have nonetheless responded to this unsupported position by furnishing testimony of an expert in the field of exhalation valves, John Bowers. Bowers stated that "under the airflows and pressure drops that are encountered in the filtering face mask, 'bounce or float' is not an occurring event or problem that investigators in the exhalation valve art need to deal with." Thus, although the motivation cited by

⁸ *In re Rouffet*, 47 USPQ2d 1453, 1456 (Fed. Cir. 1998) ("When a rejection depends on a combination of prior art references, there must be some teaching, suggestion, or motivation to combine the references.").

⁹ *In re Beattie*, 24 USPQ2d 1040, 1042 (Fed. Cir. 1992) ("The question is whether there is something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination.").

¹⁰ *Rouffet* at 1457. ("If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue. Furthermore, rejecting patents solely by finding prior art corollaries for the claimed elements would permit an examiner to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat the patentability of the claimed invention. Such an approach would be "an illogical and inappropriate process by which to determine patentability.").

¹¹ *In re Lee*, 61 USPQ 1431, 1433 (Fed. Cir. 2002).

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the Examiner does not exist, the Examiner nonetheless totally ignores the evidence of record in the Bowers Affidavit. The Examiner's refusal, in either instance, to cite any prior art source in support of his views for making the combination is clear legal error. The Federal Circuit has explained at length in *In re Lee* that obviousness rejections based on combinations of references are improper when there is no evidence within the four corners of the record, to support the reasoning behind making the combination. Conclusory statements simply are not evidence.¹²

Not only has the Patent Office erred by failing to supply the record with any evidence for making the combination, the Patent Office also has still further erred in totally disregarding the testimony of Bowers. The reviewing courts have stated on numerous occasions that it is not proper for Examiners to disregard — or substitute their viewpoint for — the evidence supplied by persons who are skilled in the technology at hand.¹³ The MPEP is in accord:

Evidence traversing rejections must be considered by the Examiner whenever present. All entered affidavits, declarations, and other evidence traversing rejections are acknowledged and commented upon by the examiner in the next succeeding action....Where the evidence is insufficient to overcome the rejection, the examiner must specifically explain why the evidence is insufficient. General statements such as 'the declaration lacks technical validity' or 'the evidence is not commensurate with

¹² See *In re Lee*, 61 USPQ2d at 1434 ("With respect to Lee's application, neither the examiner nor the Board adequately supported the selection and combination of the Nortrup and Thunderchopper references to render obvious that which Lee described. The examiner's conclusory statements that "the demonstration mode is just a programmable feature which can be used in many different device[s] for providing automatic introduction by adding the proper programming software" and that "another motivation" would be that the automatic demonstration mode is user friendly and it functions as a tutorial" do not adequately address the issue of motivation to combine. The factual question of motivation is material to patentability, and could not be resolved on subjective belief and unknown authority."); see also *In re Dembiczak*, 50 USPQ 1614, 1617 (Fed. Cir. 1999) ("Broad conclusory statements regarding the teachings of multiple references, standing alone, are not 'evidence'").

¹³ See, *In re Zeidler*, 215 USPQ 490 (CCPA 1982) ("Although perception of color may, in essence, be a 'subjective' determination, we believe that an expert's evaluation in this field is entitled to more weight than that of a layman. *In re Neave*, 54 CCPA 999, 1007, 370 F.2d 961, 968, 152 USPQ 274, 279-80 (1967). Therefore, because the qualifications of Lach and the test procedures which he employed are unchallenged, the board's holding that 'a more dramatic difference in results' is required constitutes reversible error, the board having erroneously substituted its judgment for that of an established expert in the art."); *In re Fay*, 146 USPQ 47 (CCPA 1965) ("It seems to us that one as well qualified in the highly technical art of fluoride-containing halogenated compounds as Hennig is shown to be is properly entitled to express his expert opinion, and that such an opinion is entitled to be given consideration with the other evidence in the case in determining whether the conclusion of obviousness is supported by the opinion of the examiner as to what the prior art teaches. For the reasons previously stated we do not think the prior art teachings furnish factual support for the examiner's opinion."); see also *In re Alton*, 37 USPQ2d 1578 (Fed. Cir. 1996) ("We do, however, hold that the examiner's final rejection and Answer contained two errors; (1) viewing the Wall declaration as opinion evidence addressing a question of law rather than a question of fact; and (2) the summary dismissal of the declaration, without an adequate explanation of why the declaration failed to rebut the Board's *prima facie* case of inadequate description").

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the scope of the claims' without an explanation supporting such findings are insufficient.¹⁴

If the Examiner chooses to continue down this path, applicants request that he furnish the record with an affidavit that shows why his views for making the combination are valid. Because until there is evidence in the record, which evidence clearly shows that a person of ordinary skill would have combined the teachings of Simpson with McKim, the obviousness rejection based on these references cannot be properly held to constitute a *prima facie* case of obviousness.¹⁵

Sixthly, the Simpson and McKim documents each present very good evidence of a lack of motivation to combine their respective teachings. The McKim technology was known to persons of ordinary skill before the Simpson publication. Nonetheless, Simpson did not employ the McKim technology in its flapper-style exhalation valve, even though Simpson and McKim both disclose flapper-style valves (albeit in entirely different fields). If the particular structure necessary for causing the flap to be pressed towards the seal surface would have been obvious to a person of ordinary skill in making a flapper-style exhalation valve, you would have expected a person skilled in the exhalation valve art to have used that technology in a valve like Simpson's. The Board should notice that a very long time has passed since McKim's publication in 1962 and its disclosure of a curved flapper-style valve, but that particular technology did not find its way into use in the exhalation valve art at any point over this large time span. If this aspect of the present invention would have been obvious to a person of ordinary skill, the skilled artisan in the respirator art would have been expected to employ it sometime within those years. A prolonged existence of unused technology provides very good evidence of nonobviousness.¹⁶ Simpson, which was published almost 20 years after McKim and filed more than about 12 years before the effective filing date of

¹⁴ MANUAL OF PATENT EXAMINING Procedure § 2144.03, 2100-129 (August 2001).

¹⁵ See *Lee* at 1458. (The Federal Circuit reversed a decision of the Board because it "did not, however, explain what specific understanding or technological principle within the knowledge of one of ordinary skill in the art would have suggested the combination.").

¹⁶ See *Al-Site Corp. v. Opti-Ray Inc.*, 28 USPQ2d 1915, 1922 (E.D.N.Y. 1993) ("Second, the prior art existed for many years and yet those skilled in the art never created a hanger mechanism comparable to Al-Site's patented invention. See *id.* at 1577."); see also, *Panduit Corp. v. Dennison Mfg. Co.*, 1 USPQ2d 1593, 1604-05 (Fed. Cir. 1987) ("We cannot see why the district court's first set of findings did not require a conclusion that Caveney's inventions, which had for years escaped others who sought them, 'would not have been obvious' under § 103; nor why Panduit and Dennison wasted research resources for years if Caveney's inventions were obvious to all throughout those years; nor how the prior art made Caveney's eminently successful inventions obvious to the court in 1984 when it had not made them obvious to skilled engineers (each more skilled than the 'ordinary mechanic' referred to in *Hotchkiss v. Greenwood*, 52 U.S. (11 How.) 261, 13 L.Ed. 683 (1851)) who had been designing unsuccessful or far less successful cable ties for years when Caveney's inventions were made in the 1960's.").

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the present application, also did not use this technology or find it to have been obvious. Nor did any other investigator in the filtering face mask art, either prior to or after Simpson (but before applicants' invention). Thus, the prior knowledge of the McKim technology and the long time that has elapsed since McKim's first publication, coupled with the failure to use this technology in a flapper valve system, presents very good evidence that applicants' invention would not have been obvious to a person of ordinary skill within the meaning of 35 U.S.C. § 103.¹⁷

For the above six reasons, the obviousness rejection cannot be properly sustained. Please favorably reconsider the outstanding rejection and allow this application at an early date.

Respectfully submitted,

8-6-03
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¹⁷ See *In re Ehringer*, 146 USPQ 31, 37, CCPA (1965) ("Thus over 40 years elapsed in this art prior to appellant's filing date without anyone suggesting so far as the art cited shows, a non-sag thoriated tungsten filament or any way of producing it.").